

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61F 5/00</b>	<b>A1</b>	(11) International Publication Number: <b>WO 91/16020</b> (43) International Publication Date: <b>31 October 1991 (31.10.91)</b>
<p>(21) International Application Number: <b>PCT/US90/02286</b></p> <p>(22) International Filing Date: <b>26 April 1990 (26.04.90)</b></p> <p>(71) Applicant (for all designated States except US): <b>DANNING-ER MEDICAL TECHNOLOGY, INC. [US/US]; 1145 Chesapeake Road, Columbus, OH 43212 (US).</b></p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only) : <b>PUNO, Rolando, M. [US/US]; 8204 Pipilo Place, Louisville, KY 40242 (US). MELLINGER, Phillip, A. [US/US]; 1094 Kirk Avenue, Worthington, OH 43085 (US).</b></p> <p>(74) Agents: <b>GALLOWAY, Peter, D. et al.; Ladas &amp; Parry, 26 West 61 Street, New York, NY 10023 (US).</b></p>		<p>(81) Designated States: <b>AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE*, DE (European patent)*, DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.</b></p> <p>Published With international search report.</p>
<p>(54) Title: <b>TRANSPEDICULAR SCREW SYSTEM AND METHOD OF USE</b></p> <div data-bbox="613 1024 1128 1333"> </div> <p>(57) Abstract</p> <p>An apparatus is provided for the internal fixation of the spine. The apparatus comprises two sets of implants (8) each consisting of a rod (18) and a plurality of vertebral anchors (16). The rod (18) is secured to the vertebral elements by the vertebral anchors (16). The anchor (16) includes a transpedicular screw (21) which is secured to a vertebrae. The anchor (16) further includes an anchor seat (23) which captures the screw (21) and permits micromotion between the anchor seat (23) and screw (21). This seat (23) has a rod-receiving channel (51, 52) which captures the rod (18). A cap (25) cooperates with the seat (23) to secure the rod (18) in the anchor (16). A nut (27) screws down from the top of the assembly onto the seat (23) to cause rod (18) receiving flanges (46, 47) in the cap (23) to apply a compressive force to the rod (18). A method of therapy is presented in which the present implants (8) are inserted surgically into a patient.</p>		

• See back of page

BEST AVAILABLE COPY

## DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

## FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TC	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

WO 91/16020

PCT/US90/02286

-1-

## Transpedicular screw system and method of use

5

This invention relates generally to an apparatus for immobilization of the spine, and more particularly, to an apparatus for posterior internal fixation of the spine as well as to a method of therapy which utilizes the device.

10

15

20

25

30

35

Various methods of spinal immobilization have been known and used during this century in the treatment of spinal instability and displacement. The preferred treatment for spinal stabilization is immobilization of the joint by surgical fusion, or arthrodesis. This method has been known since its development in 1911 by Hibbs and Albee. However, in many cases, and in particular, in cases involving fusion across the lumbosacral articulation and when there are many levels involved, pseudoarthrosis is a problem. It was discovered that immediate immobilization was necessary in order to allow a bony union to form. Early in the century, post operative external immobilization such as the use of splints and casts was the favored method of treatment, however, as surgical techniques have become more sophisticated, various methods of internal and external fixation have been developed.

Internal fixation refers to therapeutic methods of stabilization which are wholly internal to the patient and include commonly known devices such as bone plates and pins. External fixation in contrast involves at least some portion of the stabilization device which is external to the patient's body. Internal fixation is now the favored method of immobilization since the patient is allowed greater freedom with the

WO 91/16020

PCT/US90/02286

-2-

elimination of the external portion of the device and the possibility of infections, such as pin tract infection, is reduced.

Some of the indications treated by internal fixation of the spine include vertebral displacement and management such as kyphosis, spondylolisthesis and rotation; segmental instability, such as disc degeneration and fracture caused by disease and trauma and congenital defects; and tumor diseases.

A common problem with spinal fixation is the question of how to secure the fixation device to the spine without damaging the spinal cord. The pedicles are a favored area of attachment since they offer an area that is strong enough to hold the fixation device even when the patient suffers from osteoporosis. Since the middle 1950's, methods of fixation have utilized the pedicles. In early methods, screws extended through the facets into the pedicles. More recently, posterior methods of fixation have been developed which utilize wires that extend through the spinal canal and hold a rod against the lamina (such as the Luque system) or that utilize pedicular screws which extend into the pedicle and secure a plate which extends across several vertebral segments (such as the Steffee plate).

U.S. Patent No. 4,805,602 to Puno, et al presents a system sharing advantage of both the wired implants and the plate. Specifically, that screw and rod system provides a rigidity which is intermediate between the wired implant and the plate systems and may be contoured to any plane.

The present invention represents an improvement in the technology and in the therapy advanced in U.S. Patent No. 4,805,602. In particular, this invention greatly reduces the time required to perform the spinal operation as compared to the prior invention. As an example of such a reduction, the time for inserting the anchors may be cut from hours to around an hour.

WO 91/16020

PCT/US90/02286

-3-

Such a time saving represents a significant reduction in the risk associated with a surgical procedure. Further, the new design may be easier to use as the chances of cross-threading the nut unto the anchor are reduced and the nut is more accessible for tightening. This is of particular significance in the bloody environment which obscures the spinal surgeon's access to the fixation device. The present device achieves this accessibility and attendant time savings without sacrificing the mechanical benefits of the earlier design. In particular, the anchor is designed so that it is not overly obtrusive. More specifically, the nut is thin and further is chamfered to reduce bulk and yet includes a thread design to achieve sufficient compression on the rod. The anchor system presents a flush upper surface and the total system is elegant and effective. Each anchor seat is secured by a cancellous screw which cooperates through a sloped bore in the anchor seat so as to provide a limited ball and socket motion. The design of the present invention incorporates a method of therapy for treating a spinal indication utilizing this internal fixator.

In particular, the present invention is viewed as having an application in the stabilization of the thoracolumbar, lumbar, and sacral spine. There are problems of fixation unique to this area of the spine such as the fact that the lumbar spine is normally lordotic and this lordosis must be preserved. In addition, indicated spinal decompression often requires a destabilization of the spine posteriorly. This may result in instability unless fusion is done, and fusion will often fail to become solid unless effective internal fixation is used. Finally, the points of sacral fixation are the weakest point of fixation. These problems are addressed by the present invention.

WO 91/16020

PCT/US90/02286

-4-

5 Prior art devices for posterior spinal fixation are discussed above as including the Steffee plate and the Luque System. A complete discussion of various internal devices are included in L. Wiltse, "Internal Fixation of the Lumbar Spine," Clinical Orthopaedics and Related Research, February 1986, No. 203, pp. 2-219. Known implant configurations include facet screws, 10 double distraction systems, compression distraction systems, springs, spinous process plates, wired implants and transpedicular screw and plate systems.

Common distraction and compression systems utilize a threaded rod and hooks which engage selected 15 transverse lamina of the vertebrae. Examples of such systems include the Harrington distraction system sold by Zimmer USA, Inc., the Keene system shown in U.S. Patent No. 4,269,178 and the Lewis-Greenlaw System illustrated in U.S. Patent No. 4,085,744. U.S. Patent 20 No. 3,648,691 to Lumb, et al shows the use of spinous process plates.

Wired implants are favored by some orthopedic surgeons because of the flexibility of the system. Dr. Eduardo Luque has developed a wired implant system where 25 two L-shaped rods are secured along their long sides to the vertebral laminae by means of wires which pass through the vertebral foramina. The short legs of the rods extend across the vertebrae between the spinous process. A similar wired implant is shown in U.S. Patent No. 4,604,995 to Stephens, et al. 30

Transpedicular screw and plate systems rely on a screw threaded into a reamed canal generally positioned perpendicular to the longitudinal axis of the spine and horizontal or parallel to the transverse plane 35 of the vertebral body. The screws engage a plate which has been bent to conform to the normal curvature of the spine or to the points of desired reduction. One screw

WO 91/16020

PCT/US90/02286

-5-

5 and plate system which has been used with significant success is the Steffee system. In this system, the screws are inserted first, the spine plates are then inserted over the pedicle screws and then posterior tapered nuts are screwed on. The screws are tightened bilaterally until the plate is locked between two nuts.

10 While the wired implants have the advantages of facilitating vertebral alignment, permitting variation of the device to allow for variations in individual spines, this method of fixation includes the increased risk of damage to the neural structures. This risk can be countered by the use of transpedicular screws and plates. The pedicle presents an area for fixation of sufficient size and depth, that under careful conditions, the risk of damage to the neural elements (i.e., 15 spinal cord and or nerve roots) is reduced. On the other hand, the use of plates with the screws rigidly linked results in the direct transfer of loads at the bone-screw interface which is the weakest link in the fixation spine construction. This can result in break- 20 age of the screw or failure of the bone-screw interface prior to achieving fusion. In addition, the current plate designs are bulky and leave little surface for bone grafting and they cannot be contoured to account for lateral curvature of the spine (i.e., scoliosis). 25

30 The present invention utilizes a rod and vertebral anchors which holds the rod in position. Each anchor is secured to the vertebrae by a transpedicular screw member.

35 The screw and rod system of the present invention combines favorable attributes discussed above of wire implants and of screw plate systems. In particular, the present invention has an object of providing a fixation system which adequately immobilizes

WO 91/16020

PCT/US90/02286

-6-

the lumbosacral area, allows relatively simple and risk-free insertion and provides adequate area for bone grafting.

5 Thus, the present invention combines advantages of the known devices as it provides suitable immobilization, in particular of the lumbosacral region, it allows for adaptation to individual patient characteristics such as degree of sagittal and/or coronal plane curvature; it allows for safe and relatively risk-free insertion; and it permits sufficient area for bone  
10 grafting.

Further, the present invention presents an improvement over the previous rod and anchor system as it streamlines the surgical procedure and increases the  
15 ease of insertion while maintaining the favorable attributes of the other system. Specifically, one less part is required and less time is required in preparation of the bony surface to receive the implant.

20 In order to achieve these advantages, the present design utilizes two implant sets on either side of the spinous processes. Each implant set includes a 0.25 inch diameter stainless steel (316L) rod which spans the vertebrae to be immobilized. Generally, an implant set is used on each side of the spinous process  
25 on the posterior side of the lamina and the transverse process. The rod is held in position by a stainless steel vertebral anchor which captures the rods. The anchor has a seat member which is secured to the vertebrae by a stainless steel transpedicular screw. The  
30 screw is separate from the anchor seat and thus provides for limited motion between the anchor seat and the vertebrae. In addition, this aspect of the design acts as a "shock-absorber" to prevent direct transfer of load from the rod to the bone-screw interface prior to  
35 achieving bony fusion, thereby decreasing the chance of failure of the screw or the bone-screw interface prior to achieving bony fusion. This greatly facilitates the



WO 91/16020

PCT/US90/02286

-7-

surgical procedure and therapy incorporating this device.

5 In the preferred embodiment, the anchor comprises three members; an anchor seat having a bore which receives the screw and a rod-receiving channel transverse to the screw; a cap which mates with the anchor seat to capture the rod between the rod receiving channel and the cap; and an internally threaded collar or nut which engages external threads on the anchor seat  
10 to tighten the cap into position on the rod support as it is screwed downward into position on the anchor seat.

15 FIG. 1 is a side view of a spine with the invention in place;

FIG. 2 is a side plan view of the vertebral anchor and rod of the present invention;

20 FIG. 3 is a posterior view of a vertebral body with an exploded view of the fixation device of the invention;

FIG. 4 is a cross-sectional of the anchor seat along line 4-4 with the rod shown in phantom;

25 FIG. 5 is a top plan view of the assembly;

FIG. 6 is a cross-section of the assembly shown in FIG. 4 taken along line 6-6;

FIG. 7 is a cross-section of the anchor seat and nut with the cap and screw and the rod shown in phantom;

30 FIG. 8 is a top view of the crosslink of the present invention;

FIG. 9 is a cross-section taken along line 9-9 of FIG. 8;

35 FIG. 10 is a cross-section taken along line 10-10 of FIG. 8;

FIG. 11 is a cross-section of the set screw;

WO 91/16020

PCT/US90/02286

-8-

FIG. 12 is a posterior view of the placement of the awl;

FIG. 13 is a cross-section of a vertebrae showing placement of the pedicle probe;

5 FIG. 14 is a side view showing the placement of the trial seats;

10 FIG. 15 is a cross-section of a vertebrae showing implantation of the anchor seat and transpedicular screw using a seat holder and hexagonal screw driver;

FIG. 16 is a cross-section of a vertebrae showing the transpedicular screw and the seat in position;

15 FIG. 17 is a posterior view showing installation of the rod and cap using the rod holder and cap holder;

FIG. 18 is a posterior view showing tightening of the nuts on the anchor seats;

20 FIG. 19 is a posterior view showing installation of the crosslinks; and

FIG. 20 is a posterior view showing positioning of the joining link between the crosslink and tightening of the set screw in the crosslink.

25

30 The anchor screw and rod system 10 of the present invention includes two implant sets 8 on either side of the spinous processes. Each set is comprised of a plurality of vertebral anchors 16 and a rod 18 which is of sufficient length to span the length of spine to be immobilized.

35 Each anchor 16 is positioned on the dorsal side of the vertebra and in general, a separate anchor 16 is used for each vertebrae comprising the length of spine to be stabilized. The rod 18 is held by the anchors 16 posterior to the vertebra.

WO 91/16020

PCT/US90/02286

-9-

5 The rod 18 is generally made of quarter inch stainless-steel rod (316L), but could be made of any material which has suitable biocompatibility and material strength characteristics. The rod should be able to withstand lateral bending forces and torsion since the system may be used to correct spinal displacement and curvature. On the other hand, it is important that the rod 18 can be bent to a certain extent so that the rod can be bent to the proper curvature for the individual application.

10 The vertebral anchor 16 comprises a transpedicular screw 21, an anchor seat 23, a cap 25, and a nut 27. The various anchor parts 16 can be made of any suitably strong biocompatible material such as stainless steel. The screw 21 which is shown is a standard stainless steel cancellous screw with 6.5 mm thread diameter. It is available in various lengths. The anchor 16 was designed for use with this screw since the screw is readily available, and it has a proven record in fracture fixation; and the size can be accommodated by the average adult pedicles of the lower thoracic, lumbar and the upper two sacral segments vertebrae.

20 The screw 21 includes a head 30 which accommodates a hex driver. The screw 21 includes a smooth shank 32 of 2-4 millimeters length which joins the rounded rear shoulder 34 of the head 30. After insertion, the screw 21 extends from the curve formed on the dorsal side of the posterior neural arch.

25 The anchor seat 23 is comprised of a hollow cup portion 49 which receives the screw and which includes opposing channels 51,52 to receive the rod 18. The cup 49 has a stepped central longitudinal opening 40 having an upper inner diameter section of about 0.358 and a smaller lower diameter section which slightly exceeds the diameter of the head 30 of the screw 21. This step eliminates unwanted motion between the screw 21 and the anchor 23. This lower diameter section is

WO 91/16020

PCT/US90/02286

-10-

about 0.323 of an inch. The screw 21 passes through the two sections of the opening 40 within the rod support 23 until the rear shoulder 34 of the screw 21 encounters a  
5     detaining flange 42 within the central opening 40 of the rod support 23. The flange 42 has an internal surface at an angle of about 120 degrees and defines an opening 43 which has a diameter that exceeds the diameter of the shank 32 but which is smaller than that of the head 30 of the screw 31. The diameter of the opening at the  
10     flange is about 0.27 of an inch. The internal surface of the detaining flange 42 represents a sloped shoulder 44 which forms a socket for the rear shoulder 34 of the screw head 30. Thus, when the screw 21 engages the anchor seat 23, a limited ball-and-socket joint is  
15     formed which permits freedom of movement between the rod support 23 and the screw 21.

The anchor seat 23 has two opposing channels 51,52 of the proper diameter to cradle the rod 18. The channels 51,52 form a rod-receiving cradle which is  
20     about 0.37 of an inch long..

The height of the anchor seat 23 generally determines the amount that the anchor 26 projects posterior of the vertebrae. This height ranges from 0.66 to 0.84 inches. However, if necessary, one or two  
25     washers may be added. These washers are smooth round washers having an outer diameter which corresponds to the diameter of the anchor seat, i.e., 0.5 inch, and a height of 0.063 inch. The washer fits around the screw 21 and is positioned under the seat between the bone and  
30     the seat 23. The washers are useful in indications where the patient is heavy or severely deformed.

On its external surface, the anchor seat 23 includes a threaded area 76. This area is 0.27 inch deep to the thread runout. A 45 degree chamfer is  
35     included at the top to facilitate threading the nut on the seat 23. The threads are at a count of 20 threads per inch. The nut 25 has a height of 0.19 inch and

WO 91/16020

PCT/US90/02286

-11-

includes a chamfered area 81 on its top surface. This chamfered area 81 blunts the edges of the nut and eliminates sharp edges which could otherwise irritate the soft tissues post-operatively, two opposing clamping flanges 46,47 which each extend about 0.13 inch beyond a larger diameter area 46 of the cap 25. Two such larger diameter areas 48 exist and form opposing buttressing curves where the flanges 46,47 flow into the cup portion 59 of the cap 25. These two areas 48 mate with the channels 51,52 so that the seat 23 and the cap 25 complement each other to form a cylindrical unit into which the nut 27 is threaded. On its bottom, the cap 25 includes an arch 72 transverse to the longitudinal axis of the cap 25.

The nut 27 includes internal threads 83 which engage the external threaded area 76 on the anchor seat. The nut 27 is a hex nut which can be tightened relative to the seat 25.

As the nut 27 is rotated about the anchor seat 25, it cooperates with the top side of the flange 46,47 to tighten the clamp 25 in relation to the rod support 23. The rod 18 is grasped in the tunnel 84 formed between the rod-receiving channel 54 of the anchor seat 23 and the arch 72 of the cap 25.

As a further part of this invention, a crosslink 110 may be used to stabilize the rod members 18 against torsional rotation. The crosslink 110 may be used with this implant device or with any spinal implant which utilizes rods for longitudinal stability such as the Harrington rod system. It is preferable that two crosslinks are used to form a rectangular construct. Each crosslink 110 comprises two clamps 112, each secured to the main rods 18. Specifically, each clamp 112 includes a rod receiving channel 113 which accommodates the rod 18 and is locked into position relative thereto by a first set screw received in bore 114. The clamp further includes a link opening 118 which has a

WO 91/16020

PCT/US90/02286

-12-

well 119 to accommodate a link 117 axially transverse to the main rod 18. This link 117 may be, for example, a 4 mm Steinmann pin. The link 117 is locked into position by a second set screw which biases the link 117 into the well 119. The set screws 115 include a hexagonal opening 120 to receive a corresponding screwdriver. The screws 115 further include a terminal bevel at a 45 degree angle to facilitate locking the rod and link, respectively.

A method of therapy for use of the present device is described as follows:

Initially, the area of implantation is surgically approached. A longitudinal posterior midline incision is made over the spine. The incision is carried through the subcutaneous tissue and the fascia to the tips of the spinous processes. Subperiosteal dissection is performed over the laminae and transverse processes. The facet capsule and articular cartilage are removed in preparation for fusion.

The pedicle is located using an awl 80. The awl 80 is used to make a hole 4 mm deep at the intersection of a line drawn transversely through the midportion of the transverse process and a line drawn longitudinally through the lateral margin of superior articular facet.

A pedicle hole is made using a pedicle probe 85. The pedicle probe is inserted into the hole initially created by the awl 80 and rotated back and forth in a 90 degree arc of motion with a very gentle downward pressure. The surgeon feels a relatively soft gritty sensation of the cancellous bone within the pedicle and vertebral body during this procedure. The shaft of the probe 85 should end up at an angle of 10 to 15 degrees from the midline of the spine when used in the lumbar region. Great care should be taken not to penetrate the anterior cortex of the vertebral body with the probe 85.

WO 91/16020

PCT/US90/02286

-13-

5 The depth of the hole is determined by using  
the graduated markings on the pedicle probe 85. The  
appropriate size screw is then chosen for that particu-  
lar pedicle. The same technique is repeated for the  
remaining pedicles that need to be instrumented.  
10 Roentgenographic assistance using plain radiographs or  
fluoroscopy may be recommended for proper insertion of  
the pedicle probe 85 and screw into the pedicle. Both  
anterior-posterior and lateral views are taken with  
metal markers in the holes of the pedicles to assure  
proper hole direction prior to insertion of the screws.

15 After the hole has been created, one of four  
sizes of anchor seats is then selected depending on the  
height needed for the rod to rest above the fusion bed.  
Trial anchors 91 may be inserted on rods 92. Washers  
are provided if additional height is needed.

20 The surgeon sequentially inserts an appro-  
priate transpedicular screw 21 and anchor 23 seat  
assembly into each pedicle being instrumented. This is  
accomplished by using a hexagonal screwdriver 97. At  
the same time, the seat holder 98 grips the seat,  
thereby preventing rotation when the screw 21 is finally  
tightened.

25 After all the screws and anchor seats are in  
place, an appropriate length of 6.35 mm rod is chosen  
and contoured with a French bender to fit the seats.  
The rod 18 is placed using a rod holder 100 and secured  
on the seats with caps which are placed over the rod  
using a rod holder 101 and nuts which are tightened down  
30 over the cap with the use of a T-wrench 105.

The procedure is repeated on the other side of  
the spine over the same number of vertebral levels.

35 Finally, the crosslinks 110 may be applied for  
added torsional stability. The crosslink is composed of  
two clamps 112, each of which is secured to one of the  
two main rods with set screws 115. The clamps are then  
bridged together by a 4 mm Steinmann pin which acts as

WO 91/16020

PCT/US90/02286

-14-

a crosslink 117 which is cut to the length equivalent to the distance between the clamps. The Steinmann pin is secured to the clamp 117 with a second set screw. It is recommended that at least two sets of crosslinks are used to provide a more stable construct.

5

In the case of arthrodesis, the fusion portion of the procedure is carried out in standard fashion. However, it is recommended to place some of the bone grafts in the lateral gutter after making the pedicle hole prior to screw insertion. The presence of the instrumentation can block the visualization of the fusion bed necessary for the proper placement of the graft. The remainder of the bone grafts are placed on the fusion bed after the instrumentation is completed.

10

15

While in accordance with the Patent Statutes, the best mode and preferred embodiment has been set forth, the scope of the invention is not limited thereto, but rather by the scope of the attached claims.



WO 91/16020

PCT/US90/02286

- 15 -

C L A I M S

1. A fixation device for the stabilization of one or more bone segments, comprising at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

2. A fixation device according to claim 1, wherein said anchor seat means includes an internal bore through which said screw means projects, and wherein said screw means comprises a screw having a rounded head and said internal bore terminates in an annular flange which cooperates with said rounded head.

3. A fixation device according to claim 2, wherein said anchor seat means includes external threads and said securing means comprises a nut having internal threads and said internal threads cooperate with said external threads to secure said nut to said anchor seat means, and wherein the anchor seat means has a channel to receive said rod and said cap means has an opposing larger diameter portion which complements said channel and said larger diameter portion terminates in rod receiving flanges and said nut cooperates with said rod receiving flanges to apply said

---

WO 91/16020

PCT/US90/02286

- 16 -

compression force to said rod.

4. A fixation device according to claim 3, wherein said lower bone interface surface of said anchor seat means has a diameter of less than about 0.6 inch and said anchor projects less than 0.95 inch from said bone surface.

5. A device for the stabilization of one or more bone segments, comprising at least two anchors and a rod, said anchors each comprising a screw, an anchor seat, a cap, and a nut, said screw having a shank joined to a head, said head having a rounded profile where it joins said shank; said anchor seat having an internal bore, said screw projecting through said bore to be received by said bone segment and said bore including a shoulder which cooperates with the rounded profile of the screw head and said anchor seat further including external threads and a channel to receive said rod; said cap having a smaller outer diameter portion which is received within said anchor seat bore and a large outer diameter portion forming at one end an arch including opposing rod holding flanges; said larger outer diameter portion mating with said rod receiving channel whereby said rod is captured between said arch and said channel; and a nut including top and bottom surfaces and having internal threads which mate with the external threads of the anchor seat and said nut being posterior to said rod and tightening down toward rod whereby said bottom surface engages said opposing rod holding flanges and causes said cap to apply a compressive force to said rod.

6. A device according to claim 5, wherein said device comprises two sets of implants, each of said implant sets comprising a rod and at least two of said anchors.

7. A device according to claim 6, wherein said device further comprises two crosslinks, each of which links the rod of one implant set to the rod of the other implant set.

8. A method of therapy comprising the surgical implantation of a fixation device in a spine, said fixation device comprising a rod and at least two anchors, each of

WO 91/16020

PCT/US90/02286

- 17 -

said anchors having screw means, seat means forming a rod receiving channel, cap means including a rod-holding arch and securing means, said method comprising the steps of exposing the area including at least two vertebrae of spine to be implanted, preparing the bone of said area by flattening a surface to receive each of said seat means and by forming a hole in the pedicle of each vertebrae to receive each of said screw means, joining each of said seat means to each of said pedicles by screwing each said screw means in each of said holes, aligning the rod receiving channels of each of said seat means and inserting said rod within said channel, placing a cap over the rod for each anchor so that the rod holding arch of each cap cooperates with the rod receiving channel of each seat means and to encircle said rod so that the cap mates with the seat, tightening a securing means for each of said anchors so that the anchor applies a compressive force on said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

9. The use of a device for the stabilization of one or more bone segments, said device comprising at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is

WO 91/16020

PCT/US90/02286

- 18 -

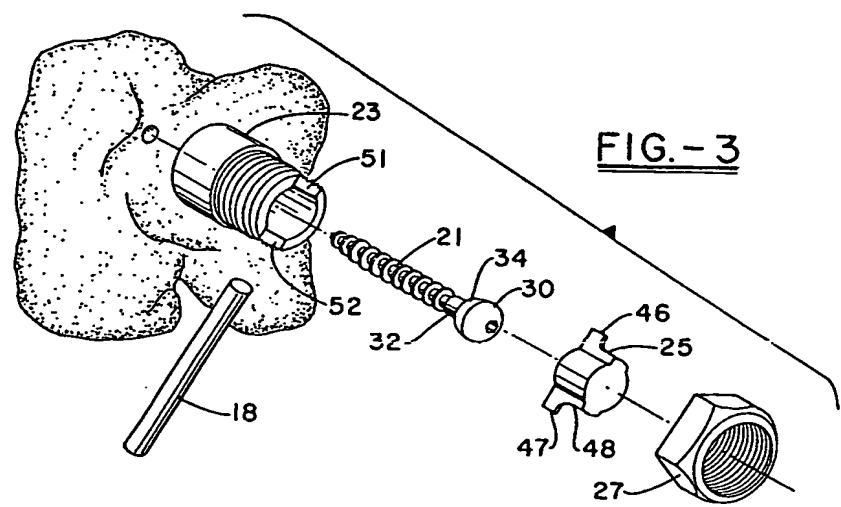
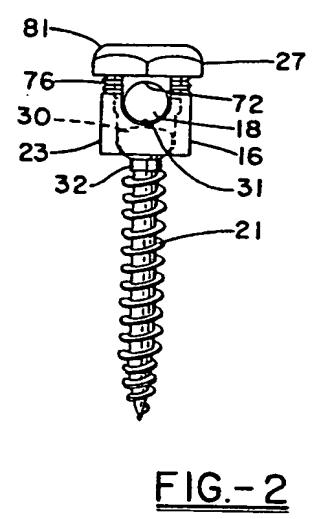
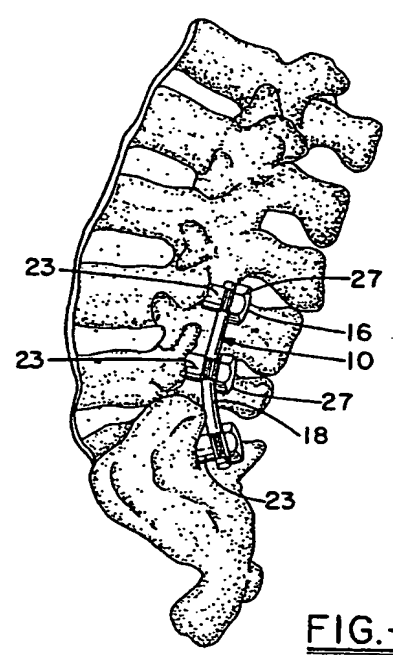
posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

10. The use of the following components to create a device for the stabilization of one or more bone segments, said components including at least two anchors and an elongated stabilizer, said anchors each comprising screw means which secures said anchor to said bone segment, anchor seat means which has a lower bone interface which is operatively joined to said bone segment by said screw means and has a portion spaced apart from said bone interface surface and said anchor seat means cooperating with said screw means so as to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having means to receive said stabilizer, cap means which cooperate with said anchor seat means to capture said stabilizer, and securing means which cooperates with said anchor seat portion which is spaced apart from said bone interface surface and which is posterior to said rod and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the rod-receiving channels is facilitated and transfer of load from the rod to the interface of the spine and the screw is inhibited.

WO 91/16020

PCT/US90/02286

- 1 / 7 -



SUBSTITUTE SHEET

WO 91/16020

PCT/US90/02286

- 2 / 7 -

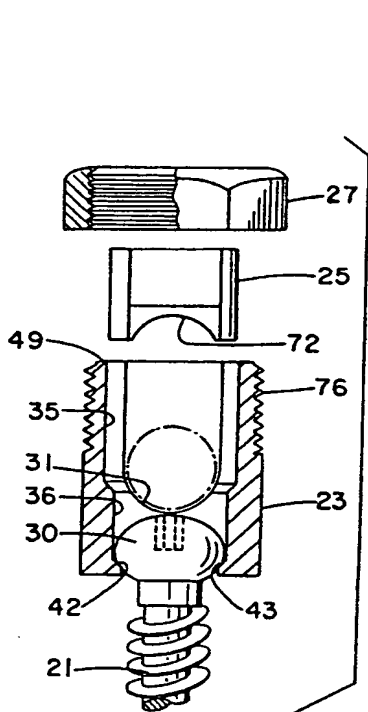


FIG.-4

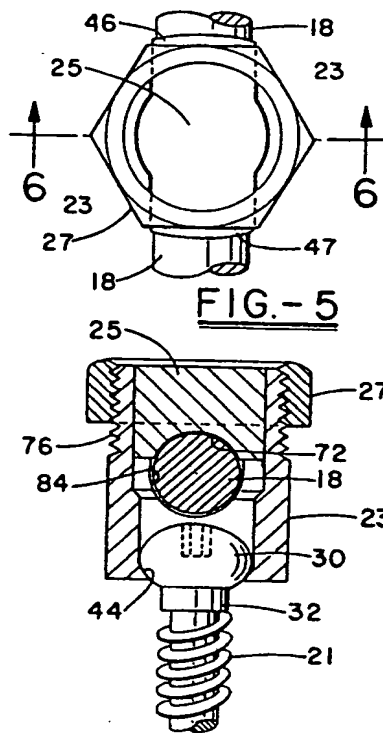


FIG.-5

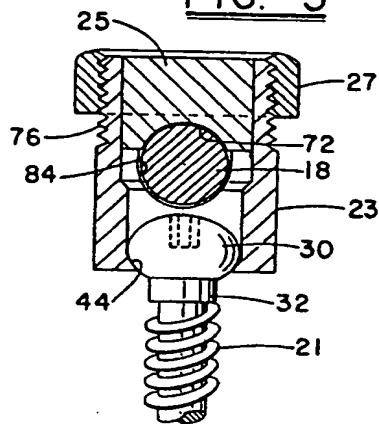


FIG.-6

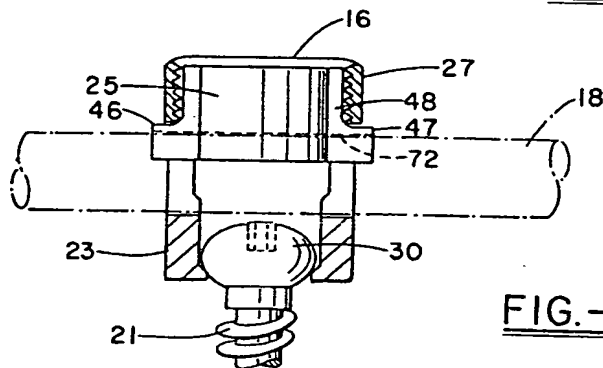


FIG.-7

SUBSTITUTE SHEET

WO 91/16020

PCT/US90/02286

3 / 7

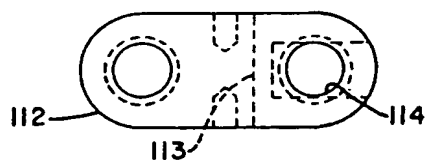


FIG. - 8

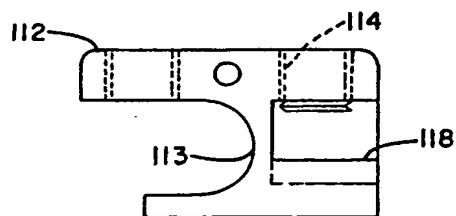


FIG. - 9

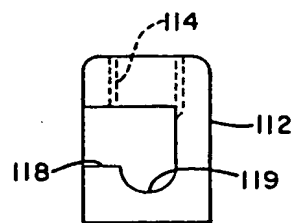


FIG. - 10

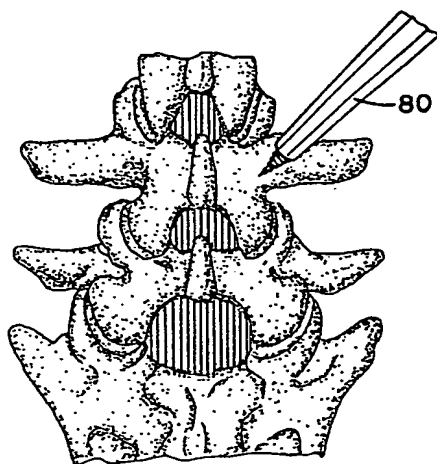


FIG. - 12



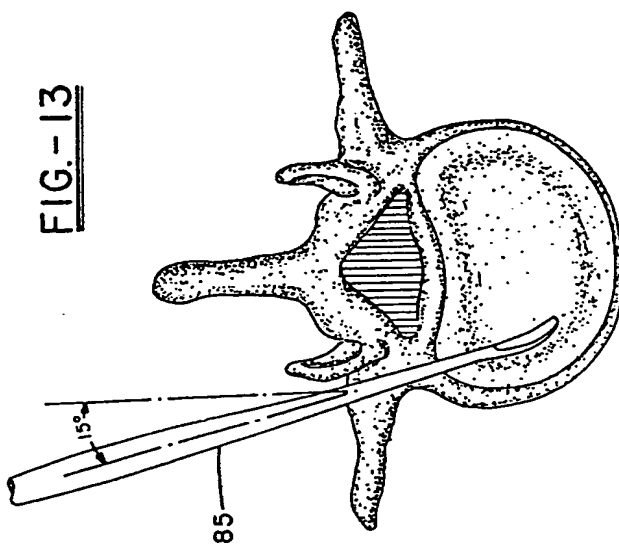
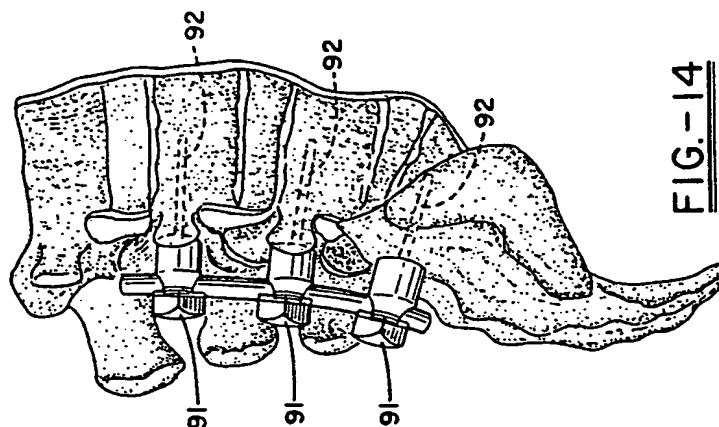
FIG. - 11

SUBSTITUTE SHEET

WO 91/16020

PCT/US90/02286

4 / 7



SUBSTITUTE SHEET



WO 91/16020

PCT/US90/02286

5 / 7

FIG.-16

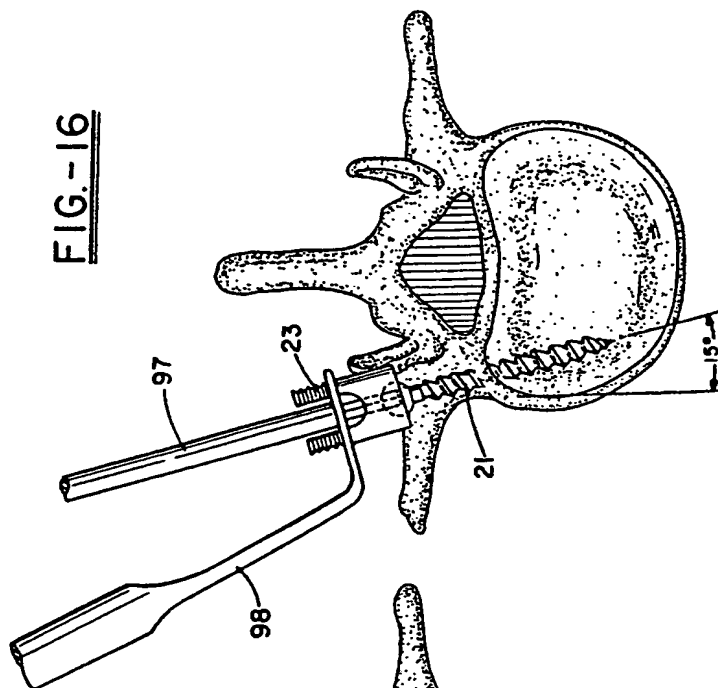
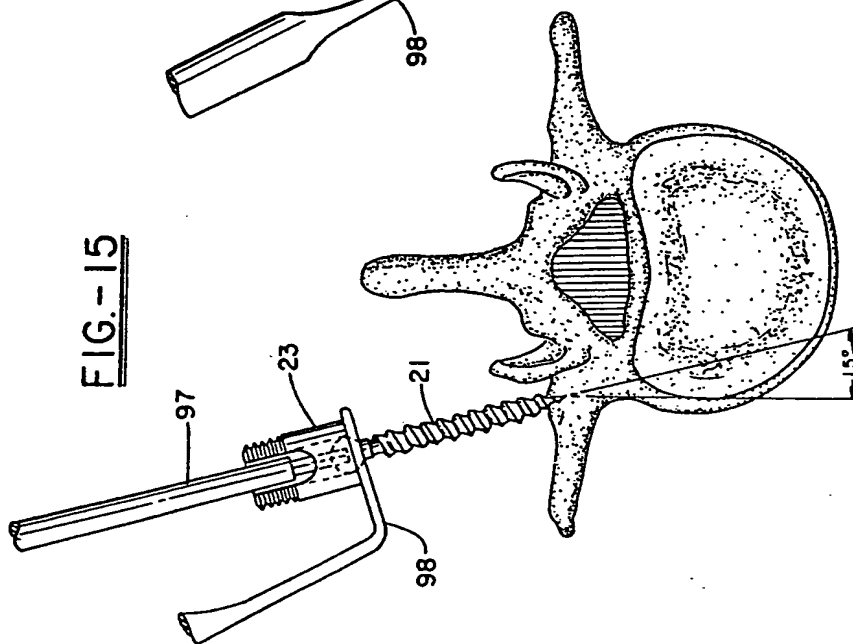


FIG.-15



SUBSTITUTE SHEET

WO 91/16020

PCT/US90/02286

6 / 7

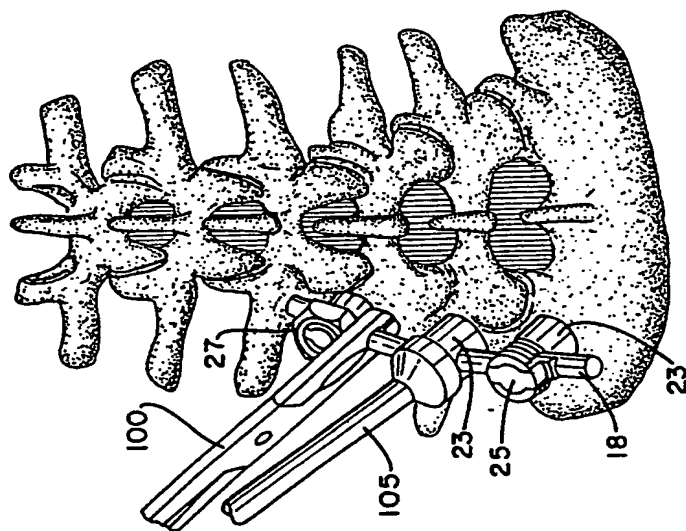


FIG. -18

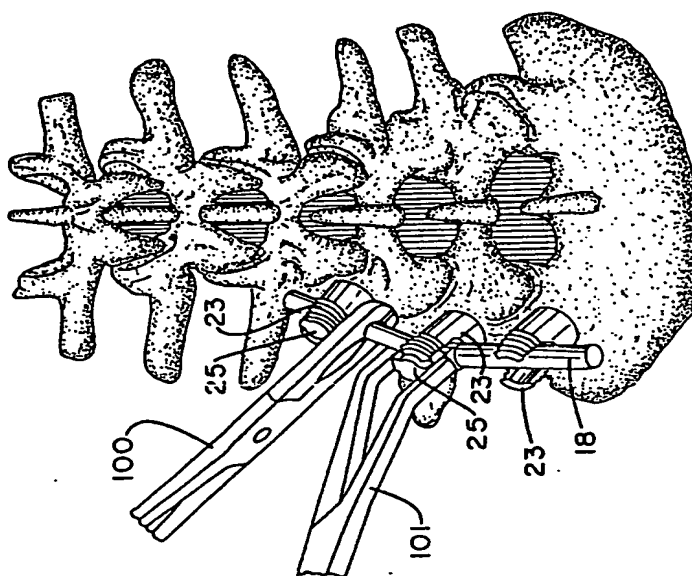


FIG. -17

SUBSTITUTE SHEET

WO 91/16020

PCT/US90/02286

7 / 7

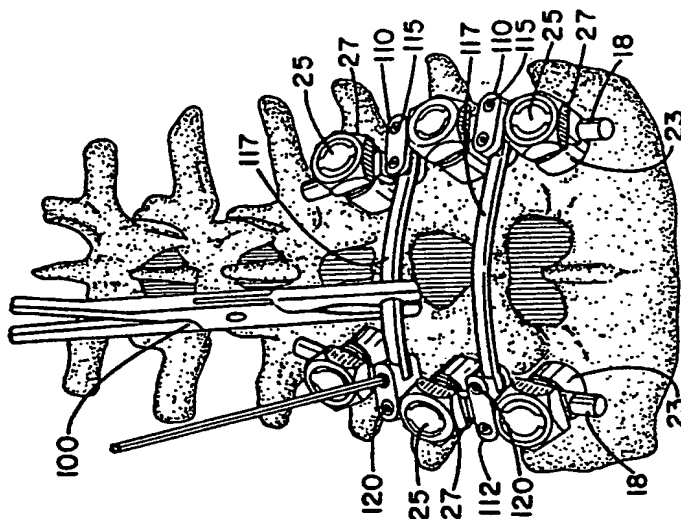


FIG.-20

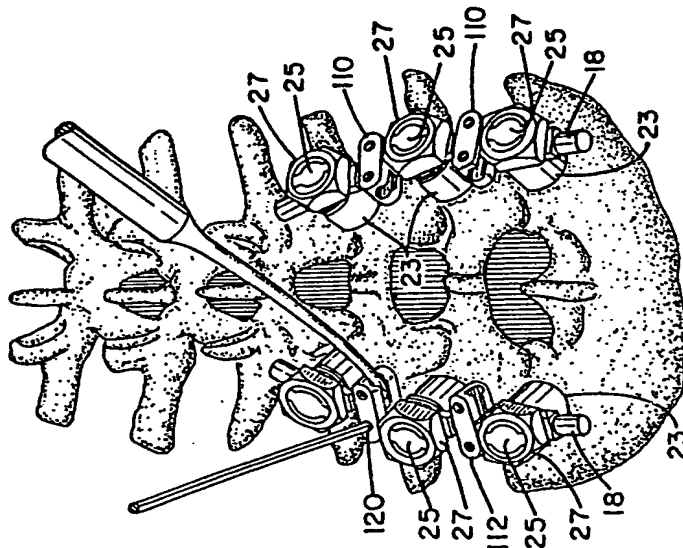


FIG.-19

SUBSTITUTE SHEET

## INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/02286

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) \*

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): [A61F/500] A61F 5/00

U.S. CL: 128/69, 606/61

## II. FIELDS SEARCHED

Minimum Documentation Searched \*

Classification System :

Classification Symbols

U.S.

403/342,399; 411/400,401  
606/60,61,72,73; 623/16,17; 128/69Documentation Searched other than Minimum Documentation  
to the extent that such Documents are included in the Fields Searched \*

## III. DOCUMENTS CONSIDERED TO BE RELEVANT \*\*

Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
X Y	US, A, 4,805,602 (PUNO ET AL.) 21 February 1989 See the entire document.	1-2 3-10
A	US, A, 4,653,481 (HOWLAND ET AL.) 31 March 1987 See the entire document.	1-10
A	US, A, 4,719,905 (STEEFEE) 19 January 1988 See the entire document.	1-10
A	US, A, 4,658,809 (ULRICH ET AL.) 21 April 1987 See the entire document.	1-10
A	US, A, 4,611,580 (WU) 16 September 1986 See the entire document.	1-10
A	US, A, 4,913,134 (LUQUE) 03 April 1990 See the entire document.	1-10
A	US, A, 4,763,644 (WEBB) 16 August 1988 See the entire document.	

\* Special categories of cited documents: \*\*

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

## IV. CERTIFICATION

Date of the Actual Completion of the International Search \*

08 AUGUST 1990

International Searching Authority :

ISA/US

Date of Mailing of this International Search Report \*

14 FEB 1991

Signature of Authorized Officer \*\*

MICHAEL A. BROWN

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☒ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☐ **FADED TEXT OR DRAWING**

☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**